

Date of Approval: June 24, 2013

FREEDOM OF INFORMATION SUMMARY

ORIGINAL NEW ANIMAL DRUG APPLICATION

ANADA 200-524

Mupirocin Ointment 2%

Mupirocin

Ointment

Dogs

For the topical treatment of canine bacterial infections of the skin, including superficial pyoderma, caused by susceptible strains of *Staphylococcus aureus* and *Staphylococcus intermedius*

Sponsored by:

Putney, Inc.

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-524

B. Sponsor

Putney, Inc.
400 Congress St., suite 200
Portland, ME 04101

Drug Labeler Code: 026637

C. Proprietary Name

Mupirocin Ointment 2%

D. Established Name

mupirocin

E. Pharmacological Category

Antimicrobial

F. Dosage Form:

Ointment

G. Amount of Active Ingredient

2% (20 mg/g)

H. How Supplied

22 g tube

I. Dispensing Status

Rx

J. Dosage Regimen

Prior to treatment, the lesion should be cleansed. Mupirocin Ointment 2% should be applied to the affected area twice a day. Apply a sufficient amount of ointment to completely cover the infected area. Maximum duration of treatment should not exceed 30 days.

K. Route of Administration

Topical

L. Species/Class

Dogs

M. Indication

Mupirocin Ointment 2% is indicated for the topical treatment of canine bacterial infections of the skin, including superficial pyoderma, caused by susceptible strains of *Staphylococcus aureus* and *Staphylococcus intermedius*.

N. Reference Listed New Animal Drug

BACTODERM; mupirocin; NADA 140-839; Zoetis Inc.

II. BIOEQUIVALENCE:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act of 1988, an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (reference listed new animal drug). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the reference listed new animal drug (RLNAD), which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of demonstrating bioequivalence (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Putney, Inc. was granted a waiver from the requirement to demonstrate bioequivalence for the generic product Mupirocin (mupirocin) Ointment 2%. The generic product is administered as an ointment, contains the same active ingredient in the same concentration and dosage form as the RLNAD, and contains no inactive ingredients that may significantly affect the bioavailability of the active ingredient. The RLNAD is BACTODERM (mupirocin) Ointment 2%, sponsored by Zoetis Inc. under NADA 140-839, and was approved for use in dogs on October 5, 1988.

III. EFFECTIVENESS:

CVM did not require effectiveness studies for this approval.

IV. TARGET ANIMAL SAFETY:

CVM did not require target animal safety studies for this approval.

V. HUMAN FOOD SAFETY:

Data on human food safety, pertaining to drug residues in food, were not required for approval of this application. This drug is approved for use in dogs, which are not food producing animals.

VI. USER SAFETY:

CVM did not require user safety studies for this approval.

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Mupirocin Ointment 2%:

- Keep out of reach of children.

VII. AGENCY CONCLUSIONS:

This information submitted in support of this ANADA satisfies the requirements of section 512(n) of the Federal Food, Drug, and Cosmetic Act and demonstrates that Mupirocin Ointment 2%, when used according to the label, is safe and effective.